

ATTACHMENT 7 - 510(k) Summary**1. Applicant's Name and Address**

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2. Name of the Device

Trade Name: ITI Protection Healing Cap
 Common Name: Healing Cap
 Classification Name: Accessory to a dental implant (21 CFR 872.3640)

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

Nobelpharma's Bränemark System Healing Caps (K Number 925780)
 Calcitek's Abutment Comfort Caps (K Number unknown)
 Interpore International's Abutment Complete Sealing Caps (K Number 912734)
 Steri-Oss' Healing Cap (K Number unknown)

4. Description of the Device

The ITI Protection Healing Cap is a device which is mounted onto an ITI implant after the abutment has been placed into the implant and serves to protect the outer configuration of the abutment and which the clinician can modify to maintain and condition the precise contours of the soft tissue during the prosthetic phase. The primary indication for the Protection Healing Cap is in the esthetic zone of the oral cavity where soft tissue conditioning is essential to achieve an optimal esthetic result with implant-borne restorations. The protection healing caps remain in place for approximately 2 weeks while the final restoration is being constructed.

The ITI Protection Healing Cap is available in two sizes. The small cap has a diameter of 5.8 mm and a height of 4.0 mm. The large cap has a diameter of 6.2 mm and a height of 5.0 mm. The Protection Healing Caps are designed with a 65° bevel which extends 0.5 mm (small) to 0.7 mm (large) beyond the outer edge of the implant making it possible to modify the dimension of the caps.

The following table shows the dimensions of the ITI Protection Healing Caps:

Article Number	11151X	11152X
Diameter	5.8 mm	6.2 mm
Height	4.0 mm	5.0 mm

After the abutment has been placed into the implant, the clinician places the protection healing cap over the abutment. If necessary, after trying in the healing cap the clinician

can remove the cap and modify it to the desired shape with a sandpaper disc. This reshaping of the cap allows the clinician to achieve a precise shape which will maintain and condition the soft tissue contour necessary in the esthetic zone. If reshaped, it is recommended that the clinician then polish the protection cap. The cap is screwed into place over the abutment with an occlusal screw which is tightened to a recommended torque of 50 Ncm. At the final prosthesis delivery the protection cap is removed and disposed.

The ITI Protection Healing Caps are composed of Polyetheretherketone (PEEK) which is extruded from its granulated form and lathed to form the caps. The granulated form of PEEK is manufactured by Victrex Limited.

5. **Intended Use of the Device**

The intended use of the ITI Protection Healing Caps is to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the prosthetic phase to achieve an esthetic result with the final restoration. The primary indication for the Protection Healing Cap is in the esthetic zone of the oral cavity where soft tissue conditioning is essential to achieve an optimal esthetic result with implant-borne restorations.

6. **Summary of Technological Characteristics of Device Compared to Predicate Devices**

FEATURE	PROPOSED DEVICE	PREDICATE DEVICES			
	ITI Protection Healing Cap	Nobelpharma Brånemark Healing Caps	Calcitek Abutment Comfort Caps	Interpore Int'l Abutment Sealing Caps	Steri-Oss Healing Cap
<i>Intended Use</i>					
To protect the outer configuration of the abutment and maintain and condition soft tissue.	Yes	Yes	Yes	Yes	Yes
<i>Material</i>					
Plastic	Yes	Yes	Yes	Yes	Yes
<i>Design</i>					
Diameter	5.8 mm - 6.2 mm	4.5 mm - 6.5 mm	4.0 mm	4.0 mm - 6.0 mm	3.8 mm
Height	4.0 mm - 5.0 mm	2.7 mm	5.0 mm	2.0 mm	3.0 mm
Placed over the abutment during the prosthetic phase.	Yes	Yes	Yes	Yes	Yes